



## REMARKS

Applicants again want to thank the Examiner for the courtesy of discussing this application with their representative on November 2, 2006. During the interview, Claims 1, 7 and 8 were discussed. Amending Claim 1 to define the ester as hydrolysable under the conditions of step i) and amending Claim 8 to replace "benzyl esters" and "cyanomethyl esters" with "benzyl ester" and "cyanomethyl ester" were discussed. The submission of a declaration to explain the stability testing defined in Claim 7 was also discussed.

Claims 1-10 are in this application

Claim 8 has been amended to replace "benzyl esters" and "cyanomethyl esters" with "benzyl ester" and "cyanomethyl ester." Therefore, it is respectfully requested that the rejection under 35 USC 112, second paragraph be withdrawn.

According to the Official Action, Claims 1-7, 9 and 10 are rejected under 35 USC 112, first paragraph. This is respectfully traversed.

Claim 1 has been amended to define the ester as hydrolysable under the conditions of step i). This is supported, *inter alia*, on pages 10 and 14 of the specification corresponding to paragraphs [0042] and [0064] of the published application; in the first full paragraph on page 18 of the application which corresponds to paragraph [0073] of the published application and the section "Selection of Methanesulfonic acid as the Bronsted acid" on pages 18 and 19 of the specification.




Therefore, it is respectfully requested that this rejection be withdrawn.

The rejection under 35 USC 112, second paragraph as it pertains to Claim 7 is respectfully traversed. Attached is the declaration of Prithish Ramchandra Upadhyay. Dr. Upadhyay explains that the stability testing was carried out at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$  at 75% RH in accordance with the International Conference on Harmonized (ICH) guideline for stability testing of new drug substances and products. A copy of the standard is attached. The Examiner's attention is drawn to section 2.1.7 on page 3 of the copy of the standard. It is shown that the accelerated testing for stability storage is  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$  at 75% RH. Accelerated testing is defined on page 14. Therefore, based on the above, it is clear that one skilled in the art would understand Claim 7 and it is respectfully requested that the rejection be withdrawn.

Accordingly, applicants submit that the application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



JANET I. CORD  
C/O LADAS & PARRY LLP  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NEW YORK 10023  
REG.NO.33,778(212-708-1935)